IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
SOUTHERN DIVISION
No. 7:23-cv-897

IN RE:	)
	)
CAMP LEJEUNE WATER LITIGATION	)
	)
This Document Relates To:	)
ALL CASES	)

UNITED STATES' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO STRIKE DR. BAILEY'S UNTIMELY GENERAL CAUSATION OPINIONS

(L. Civ. R. 7.1(f))

INTRODUCTION

Plaintiffs' Leadership Group's unfounded campaign against Dr. Lisa Bailey continues. This is Plaintiffs' third attempt to keep her Phase III, plaintiff-specific opinions from the Court. Plaintiffs selectively quote isolated excerpts from Dr. Bailey's reports while ignoring their substance. When that rhetoric is stripped away, what remains is not a concern about compliance with the Court's Scheduling Orders, but Plaintiffs' discomfort with Dr. Bailey's conclusions.

Plaintiffs cannot show a violation of the Court's Scheduling Orders. Dr. Bailey conducted plaintiff-specific risk assessments for all twenty-five bellwether Plaintiffs using plaintiff-specific exposure calculations. Her opinions address whether a Track 1 trial Plaintiff, considering his or her assumed level of exposure, experienced an increased risk of harm.[1] Dr. Bailey did not conduct an independent epidemiological or toxicological literature review, and she did not offer new opinions about whether any chemical could cause any Track 1 disease. Where general causation was relevant at all, Dr. Bailey relied entirely on previously disclosed Phase II opinions, as she reiterated in her report and deposition testimony.

Because Dr. Bailey's opinions are plaintiff-specific and properly belong in Phase III, there is no violation of the Court's Scheduling Orders. For these reasons, there is no need to analyze the appropriateness of an exclusion sanction under the *Akeva* factors, and Plaintiffs' motion should be denied. Even if the Court were to consider the *Akeva* factors, Plaintiffs' application of those factors to Dr. Bailey's opinions is misleading and exclusion is unwarranted.

[1] Curiously, Plaintiffs agree in separate filings that Dr. Bailey used "regulatory risk assessment for her *specific causation* assessment of the five kidney cancer Plaintiffs." D.E. 600, at 19 (emphasis added).

BACKGROUND

"To promote efficient resolution of this consolidated litigation, the [C]ourt has entered multiple scheduling orders governing phased expert discovery." (D.E. 444 at 1; "The Court's July 22 Order") (citing D.E. 270; D.E. 312; D.E. 414). The Court structured expert discovery into three phases: Phase I (water contamination), Phase II (general causation), and Phase III (specific causation, damages, and residual issues). *See* D.E. 444 at 1. Relevant here, the United States' Phase II disclosures were due February 7, 2025, and its Phase III disclosures were due April 8, 2025. *See* D.E. 312 at 1, 3. The United States timely disclosed Dr. Bailey as a Phase III expert on April 8, 2025. *See generally* US Phase III Exp. Discl. (JA Ex. 328, D.E. 487-4).

The United States later moved to exclude untimely Phase II general causation opinions contained in Plaintiffs' Phase III specific causation reports. D.E. 409, 410. In response, Plaintiffs invoked Dr. Bailey and claimed that she also provided untimely general causation opinions. D.E. 437 at 5–6. The Court granted the United States' motion in part, holding that "Plaintiffs' Phase III experts may not introduce new, independent general causation analyses[.]" D.E. 444 at 8.

Six weeks later, Plaintiffs filed another motion, this time suggesting that the Court should apply its decision generally to all experts, including the United States' experts. D.E. 515. Once again, Plaintiffs cited Dr. Bailey and claimed that she had offered untimely general causation opinions. The United States responded that Plaintiffs had filed the wrong motion and explained why Dr. Bailey's opinions were timely disclosed in Phase III. *See generally* D.E. 627. Needing to go no further, the Court agreed that Plaintiffs had filed the wrong motion and denied it. D.E. 685. Five weeks after that ruling, Plaintiffs return for a third time seeking yet again to exclude Dr. Bailey's opinions. D.E. 787.

LEGAL STANDARD

"First, the [C]ourt must determine whether the [United States'] Phase III expert reports violate the [C]ourt's pretrial scheduling orders[.]" D.E. 444 at 3. "Second, if so, the [C]ourt must determine what, *if any*, sanction is appropriate." *Id.* (emphasis added). Plaintiffs have asked this Court to strike Dr. Bailey's opinions.[2] *See* Fed. R. Civ. P. 16(f) (incorporating Fed. R. Civ. P. 37(b)(2)(A)(iii) by reference). "'[S]anctions of this sort should not be invoked lightly." *Joe Hand Promotions, Inc. v. Hayes*, No. 1:18-CV-531, 2020 WL 9848455, at *2 (M.D.N.C. June 25, 2020) (internal quotation omitted), *R. & R. adopted*, No. 1:18-CV-531, 2020 WL 9848453 (M.D.N.C. July 27, 2020). Indeed, this Court has described striking portions of an expert report under Rule 37(b)(2)(A)(iii) as a "draconian sanction." *Sepracor, Inc. v. Barr Pharms., Inc.*, No. 4:08-CV-89-H(3), 2009 WL 10873178, at *12 (E.D.N.C. Nov. 19, 2009).

ARGUMENT

Plaintiffs' motion fails because Plaintiffs cannot show any violation of the Court's Scheduling Orders. Dr. Bailey does not offer general causation opinions; her plaintiff-specific risk assessments rely on individualized exposure calculations and toxicity criteria, and her sole reference to "general causation" reflects reliance on Dr. Goodman's timely disclosed Phase II opinions. Accordingly, Dr. Bailey's opinions were timely disclosed in Phase III.

I. Dr. Bailey's Plaintiff-Specific Opinions Fall Squarely Within the Purview of Specific Causation and Consequently Were Properly Disclosed in Phase III.

This Court has previously defined the contours of general and specific causation analyses: in a general causation analysis, "an expert demonstrates that a particular type of harm can be

[2] Plaintiffs identify only one broad category of opinions that they allege are improper general causation opinions. *See* Pls.' Mem., D.E. 787, at 3–5; *see contra* Fed. R. Civ. P. 7(b)(1) (requiring that motions "state with particularity the grounds for seeking the order" and "state the relief sought"). As explained below, the United States disputes Plaintiffs' characterization that any of Dr. Bailey's opinions are general causation opinions.

caused by the exposure to a degree of scientific certainty[.]" *In re Camp Lejeune Water Litig.*, 736 F. Supp. 3d 311, 319 (E.D.N.C. 2024). In a specific causation analysis, "an expert opines that [a specific] plaintiff['s] exposure was a cause in fact of his or her harm." *Id.*; *see also Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263 (4th Cir. 1999) ("In order to carry the burden of proving a plaintiff's injury was caused by exposure to a specified substance, the 'plaintiff must demonstrate 'the levels of exposure that are hazardous to human beings generally as well as the plaintiff 's actual level of exposure.'") (internal citations omitted). Dr. Bailey's opinions fall squarely within the purview of specific causation analysis. Dr. Bailey performed plaintiff-specific analyses regarding each Plaintiff's increased risk from an assumed exposure to contaminants in the Camp Lejeune water to opine whether the Plaintiff's disease was likely caused by the exposure. Dr. Bailey's risk calculations were used by the United States' medical experts to determine whether a Plaintiff's exposure could be a cause in fact of his or her harm.

"It is well recognized that epidemiology usually provides the best evidence of general causation in toxic tort actions." *Rhyne v. United States Steel Corp.*, 474 F. Supp. 3d 733, 743 (W.D.N.C. 2020). The United States' expert epidemiologist, Dr. Julie Goodman, evaluated the epidemiological literature to evaluate whether a particular type of harm (i.e., Parkinson's disease, kidney cancer, non-Hodgkin's lymphoma, bladder cancer, or leukemia) could be caused by exposure to any of the contaminants of concern in the Camp Lejeune water. *See, e.g.,* Goodman Rep. (Bladder) at 5 (JA Ex. 75, D.E. 463-14). While Dr. Goodman opined that exposure to contaminant *X* may cause disease *Y* based on a review of epidemiological and toxicological literature, Dr. Bailey did not.[3] Rather, Dr. Bailey performed plaintiff-specific analyses. For

[3] In fact, Dr. Bailey repeatedly testified that she relied on Dr. Goodman's Phase II general causation work and systematic review of the epidemiological literature, rather than conducting an independent general causation analysis of her own. *See* D.E. 627 at 8–9 (collecting testimony in which Dr. Bailey confirmed that she was relying on the general causation opinions of Dr. Goodman).

example, instead of conducting her own review of the epidemiological literature, Dr. Bailey compared the exposure doses from epidemiological studies identified by Dr. Goodman to the potential exposure doses for each bellwether Plaintiff as determined by the United States' exposure expert, Dr. Judy LaKind. *E.g.,* Bailey Rep. (Dyer) at 42–45 (JA Ex. 375, D.E. 490-10). In doing so, Dr. Bailey evaluated, *inter alia*, how a specific Plaintiff's potential exposure compared to the levels of exposure identified in the epidemiological literature that were or were not associated with adverse health effects. *Id.*; *see also generally* United States' Mem. in Opp'n to Pls.' Mot. to Exclude Defense Expert Dr. Lisa Bailey, D.E. 670 (elaborating on Dr. Bailey's methodology).

Additionally, Dr. Bailey used the cancer and non-cancer toxicity criteria *derived by the Environmental Protection Agency* ("EPA") to calculate plaintiff-specific risks from the assumed plaintiff-specific exposures determined by Dr. LaKind. *See, e.g.*, Bailey Rep. (Kidd) at 3 (JA Ex. 513, D.E. 500-8) (explaining how EPA derives toxicity criteria); Bailey Rep. (McElhiney) at 3 (JA Ex. 543, D.E. 503-6) (same); *see also* Bailey Rep. (Kidd) at 27 (JA Ex. 513, D.E. 500-8) (citing EPA, *Toxicological Review of Trichloroethylene* (2011) for the TCE oral cancer toxicity values and inhalation unit risks).

Where EPA provided toxicity criteria for a chemical and exposure pathway, Dr. Bailey used EPA's values. Where EPA did not provide a point of departure ("POD") for a chemical and exposure pathway, Dr. Bailey extrapolated them using EPA's cancer slope factor or inhalation unit risk values. *See, e.g.*, Bailey Rep. (Kidd) at E-1 (JA Ex. 513, D.E. 500-8) (explaining how Dr. Bailey extrapolated from EPA's toxicity criteria to derive PODs for TCE and vinyl chloride). These PODs were used only in Dr. Bailey's margin of exposure ("MOE") analyses. *Id.* Similarly, Dr. Bailey used the Agency for Toxic Substances and Disease Registry's ("ATSDR") existing toxicity criteria for neurological effects with modified uncertainty factors to account for plaintiff-specific

factors, such as the fact that none of the Parkinson's disease Plaintiffs were exposed for 7 years or more. *See* Bailey Rep. (McElhiney) at 26–27 (JA Ex. 543, D.E. 503-6).

Thus, rather than performing her own general causation analysis, Dr. Bailey utilized *existing EPA and ATSDR toxicity criteria* to inform her plaintiff-specific risk assessments. Therefore, Plaintiffs' statement that "Dr. Bailey calculated . . . toxicity criteria herself," Pls.' Mem., D.E. 787, at 4, is misleading. Instead, Dr. Bailey applied EPA and ATSDR toxicity criteria to determine potential risks to the individual Plaintiffs.

Plaintiffs' argument also hinges on the false premise that Dr. Bailey offers "novel threshold calculations" in contravention of this Court's July 22 Order. Pls.' Mem., D.E. 787, at 4–5 (citing D.E. 444 at 5). But Dr. Bailey did not offer "novel threshold calculations;" in fact, she did not use thresholds for her calculations at all. Bailey Dep. Tr. at 130:7–12 (JA Ex. 618, D.E. 510-7) (". . . I didn't use a threshold for my calculations."); *see also, e.g.*, Bailey Rep. (Dyer) at 18–20 (JA Ex. 375, D.E. 490-10). Plaintiffs' argument reiterates a mistaken argument from their *Daubert* motion, in which they fault Dr. Bailey for opining "that the Camp Lejeune carcinogens exhibit a threshold dose." As the United States pointed out in response to that motion, Dr. Bailey, in using existing cancer and non-cancer toxicity criteria for her risk calculations, *conservatively assumed* that there was *no threshold* for her plaintiff-specific risk assessments. *See* D.E. 670 at 23–24.

Importantly, the PODs in the calculations that Dr. Bailey performed are not threshold doses. Rather, they are "the doses from which linear extrapolation is conducted to lower doses for the derivation of cancer toxicity criteria." Bailey Rep. (Dyer) at 37 (JA Ex. 375, D.E. 490-10). In some instances, this may be "the lowest exposure levels at which health effects have been observed," while in others, it may be "exposure levels at which *no* effects have been observed." *Id.* (emphasis added). Rather than representing the level of exposure sufficient to cause a disease, as Plaintiffs

suggest, EPA's toxicity criteria are highly conservative to better protect the most vulnerable populations. *See* Bailey Rep. (Kidd) at 3 (JA Ex. 513, D.E. 500-8). Because of the conservative nature of regulatory criteria, the PODs for the toxicity criteria are not considered "threshold values" for general causation. Indeed, exposures exceeding these levels do not indicate increased risk for disease, and risk assessments are calculated at lower levels based on the conservative assumption that there is no threshold. Bailey Rep. (McElhiney) at 19 (JA Ex. 543, D.E. 503-6) ("If someone is exposed to an amount above the [Minimum Risk Levels set by regulators], it does not mean that health problems will happen."); Bailey Rep. (Dyer) at 18 (JA Ex. 375, D.E. 490-10); Hu SC Dep. Tr. at 268:18–25 (JA Ex. 602, D.E. 508-11) (linear no threshold model is used by regulatory agencies in risk assessments). The risk assessments that Dr. Bailey performed based on the regulatory criteria are unique to the assumed exposure of each of the individual bellwether Plaintiffs.

Moreover, Dr. Bailey's comparison of each Plaintiff's exposure to the POD is a necessarily plaintiff-specific analysis. In her MOE analysis, Dr. Bailey compares the Plaintiffs' potential exposures, as calculated by Dr. LaKind, to exposure data from studies to contextualize the magnitude of Plaintiffs' exposures. Indeed, in instances where the Plaintiff's exposure was well *below* EPA's toxicity values, Dr. Bailey opined that this "provid[ed] support that adverse health effects would not be expected for the individual," Bailey Rep. (Cagiano) at 37 (JA Ex. 371, D.E. 490-6), and her risk assessments for the individual Plaintiffs show this. As Dr. Bailey also emphasized, exposures *exceeding* these values do not necessarily indicate that adverse health effects are expected. *Id.* at 16–17.

Dr. Bailey's opinions are part of the United States' Phase III experts' specific causation analysis. Because "[s]pecific, or individual causation, . . . is established by demonstrating that a

given exposure is the cause of a particular individual's disease," *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 471 (M.D.N.C. 2006), Dr. Bailey's analysis, which used the individual Plaintiffs' assumed exposure information to perform a risk assessment for each individual, shows the likelihood that an individual's disease may have been caused by his or her exposure to Camp Lejeune water. It also provides context to medical doctors about the individual Plaintiff's risk from that exposure relative to other factors that may have caused the disease. Dr. Bailey's analysis is a textbook example of an analysis "central" to a specific causation expert opinion:

> Central to offering an expert opinion on specific causation is a comparison of the estimated risk with the likelihood of the adverse event if the individual had not suffered the alleged exposure. This will differ depending on factors specific to that individual, including age, gender, medical history, and competing exposures.

Federal Judicial Center, *Reference Manual on Scientific Evidence* 645 n.31 (3d ed. 2011). This is exactly what Dr. Bailey did—she calculated each individual Plaintiff's risk, based on an assumed exposure and conservative regulatory toxicity criteria, and compared that individual Plaintiff's estimated risks with background cancer risks. *See, e.g.*, Bailey Rep. (Cagiano) at 36 (JA Ex. 371, D.E. 490-6); Bailey Rep. (McElhiney) at 43 (JA Ex. 543, D.E. 503-6). Accordingly, Dr. Bailey's opinions are not general causation opinions, and her opinions were properly disclosed in Phase III.

II. Because There Was No Discovery Violation, There Is No Need to Consider a Discovery Sanction, But Plaintiffs' Application of the *Akeva* Factors is Misleading.

The Court need not consider the *Akeva* factors in this instance. *See Akeva L.L.C. v. Mizuno Corp.*, 212 F.R.D. 306, 309 (M.D.N.C. 2002). But even if the Court were to analyze the *Akeva* factors, they do not warrant exclusion here.

First, Dr. Bailey did not offer general causation opinions in violation of the Court's Scheduling Orders. Rather, she used risk assessment principles to express opinions about the specific risks to each individual Plaintiff, incorporating exposure information she obtained from

another expert, Dr. LaKind. Thus, Dr. Bailey did not offer "*new*, *independent general causation analyses*, *such as* fresh literature reviews, novel threshold calculations, or independent causation models not previously disclosed." *See* D.E. 444 at 5. She simply performed individual risk assessments based on existing government agency toxicity criteria for the chemicals in relation to particular health outcomes.[4]

Second, contrary to Plaintiffs' argument, Dr. Bailey's opinions are important for the very reason that her opinions are not covered by any Phase II expert. Her plaintiff-specific analyses provide individual Plaintiff risk assessments for her to opine on individual causation and were also considered by the United States' medical experts for their causation opinions. Excluding her opinions would deprive the Court of critical, individualized evidence directly related to specific causation.

Third, contrary to Plaintiffs' argument, Plaintiffs are not prejudiced by the timing of the disclosure of Dr. Bailey's opinions. Dr. Bailey's reports were timely disclosed on April 8, 2025, giving Plaintiffs more than eight months of notice. Since then, Plaintiffs disclosed a rebuttal expert addressing Dr. Bailey's opinions, and deposed Dr. Bailey five months ago. And on September 10, 2025, Plaintiffs filed a *Daubert* motion challenging her testimony (although tellingly, their *Daubert* motion did not challenge any alleged "general causation" opinions). Plaintiffs cannot plausibly claim prejudice or surprise given their months-long access to Dr. Bailey's reports, their rebuttal expert, their deposition of Dr. Bailey, and their decision to file a *Daubert* motion challenging her

[4] Plaintiffs' present position is also difficult to reconcile with their own expert disclosures. In Phase III, Plaintiffs disclosed experts offering plaintiff-specific opinions about increased risk based on a comparison of toxicological literature and assumed levels of exposure to Camp Lejeune water. *See*, *e.g.*, Bird SC Rep. (Dyer) at 12 (JA Ex. 333, D.E. 487-9) ("[I]t is my opinion, to a reasonable degree of medical, scientific, and toxicological certainty, that Ms. Dyer was exposed to the relevant chemicals at Camp Lejeune at levels . . . that placed Plaintiff Terry Dyer at an increased risk of developing bladder cancer.").

testimony.

Fourth, contrary to Plaintiffs' argument, the exclusion of Dr. Bailey's opinions is not an appropriate remedy simply because the untimely general causation opinions of Plaintiffs' Phase III experts were excluded pursuant to the United States' successful motion. As described above, Dr. Bailey's opinions are not general causation opinions about whether the chemicals can cause the disease; instead, for her risk assessment analysis, she calculated individual risks based on agency toxicity criteria. Thus, Dr. Bailey's opinions are significantly different from Plaintiffs' general causation opinions that the Court appropriately excluded. As this Court has already recognized, "[t]argeted cross-examination [and] *Daubert* motions[]" (D.E. 444 at 7) are appropriate tools for Plaintiffs to challenge opinions; mischaracterizing Dr. Bailey's opinions to exclude them as a discovery sanction is not an appropriate way to challenge them.

Finally, Plaintiffs' arguments about "efficiency," "docket management," and "resolution on the merits" are misplaced. Because Dr. Bailey's opinions were timely disclosed, the disclosure promoted these factors. By contrast, Plaintiffs' attempt to exclude these highly relevant opinions as a discovery sanction seeks to undermine case management and resolution on the merits. The Court's consideration of Dr. Bailey's plaintiff-specific risk assessment opinions will assist a just resolution of these cases.

CONCLUSION

For the foregoing reasons, Plaintiffs' motion should be denied.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 22, 2025, I electronically filed the foregoing using the Court's Case Management/Electronic Case Files system, which will send notice to all counsel of record.

/s/ Joshua G. Carpenito
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